

REMARKS

Claims 1-13 and 19-34 are currently pending in the application. The claims have not been amended.

Accordingly, reconsideration and withdrawal of the pending rejections are requested in view of the instant remarks.

Drawings

As neither the Examiner nor the Patent Office Draftsperson has objected to the originally submitted drawings, Applicant understands that these drawings are acceptable.

35 U.S.C. §103 Rejections

Claims 1-13 and 19-34 have been rejected under 35 USC 103 as being unpatentable over U.S. Patent No. 6,329,564 B1 to LEBNER in view of U.S. Patent No. 5,979,450 to Baker, *et al.* (hereafter "BAKER"). The Examiner asserts that LEBNER shows all of the features of the instant invention, with the exception of a semi rigid tab as disclosed in BAKER, but that it would have been obvious to modify LEBNER to include a semi rigid tab, as taught by BAKER. Applicant traverses the Examiner's assertions. Applicants' independent claim 1 recites, inter alia,

- "a) a first component comprising...
 - ii) a semi-rigid tab attached to a portion of the top surface of the release liner, the semi-rigid tab comprising a first and a second edge, the first edge being oriented generally parallel to a first wound edge of the first anchoring member and attached to the release liner at a position intermediate in the release liner between the portion of the release liner protecting the first wound edge and the portion of the release liner protecting the edge of the first anchoring member generally opposite the first wound edge, the second edge extending unattached beyond the first wound edge;
the semi-rigid tab and release liner of the first component cooperating such that when the semi-rigid tab is flipped back onto the portion of the release liner to which it is not attached by adhesive, that portion of the release liner to which the tab is not attached remains fully adhered to the anchoring member;"

Applicants' independent claim 19 recites, inter alia,

- "a) providing a two-component device for closing a laceration or incision,

comprising:

- 2) a semi-rigid tab attached to a portion of the top surface of the release liner, the semi-rigid tab comprising a first and a second edge, the first edge being oriented generally parallel to a first wound edge of the first anchoring member and attached to the release liner at a position intermediate in the release liner between the portion of the release liner protecting the first wound edge and the portion of the release liner protecting the edge of the first anchoring member generally opposite the first wound edge, the second edge extending unattached beyond the first wound edge;

the semi-rigid tab and release liner of the second component cooperating such that when the semi-rigid tab is flipped back onto the portion of the release liner to which it is not attached by adhesive, that portion of the release liner to which the tab is not attached remains fully adhered to the anchoring member,".

Applicant submits that no proper combination of LEBNER and BAKER render obvious the above-noted features of independent claims 1 and 19.

LEBNER discloses a bandage 1 having a first flat flexible component 5 and a second flat flexible component 25, wherein each of the components (5, 25) have an upper surface with elongated connectors (15, 35) extending from the wound edge (20, 42) and lower surfaces coated with adhesive. See Col. 5, lines 45-60 of LEBNER. However, this document fails to teach or even suggest *the semi-rigid tab and release liner of the second component cooperating such that when the semi-rigid tab is flipped back onto the portion of the release liner to which it is not attached by adhesive, that portion of the release liner to which the tab is not attached remains fully adhered to the anchoring member*, as recited in at least independent claim 1 and 19.

Baker discloses a surgical incise drape 10 having a flexible film 12 coated with a pressure sensitive adhesive 14 that is covered by a release liner 16 provided with a liner handle 22. However, this document fails to teach or even suggest *the semi-rigid tab and release liner of the second component cooperating such that when the semi-rigid tab is flipped back onto the portion of the release liner to which it is not attached by adhesive, that portion of the release liner to which the tab is not attached remains fully adhered to the anchoring member*, as recited in at least independent claims 1 and 19.

Applicant submits, as neither applied document (LEBNER and BAKER) teach or suggest the above-noted features of at least independent claims 1 and 19, no proper combination of these

documents can render unpatentable the combination of features recited in the pending claims. Applicant respectfully submits that a *prima facie* case of obviousness has not been established as the applied references fails to support the Examiner's assertion.

In contrast to Applicants' invention, BAKER discloses a liner handle 22 attached to the leading edge of the liner 16, such that the liner handle may or may not be stiffer than the liner 16 to obtain benefits from use of the Baker device, Applicant submits BAKER does not disclose *that portion of the release liner to which the tab is not attached remains fully adhered to the anchoring member*, as recited in at least independent claims 1 and 19. See Col. 8, lines 45-52 of BAKER.

In fact, Applicant submits BAKER teaches away from the instant invention, i.e., BAKER discloses that the liner handle 22 does not have to be stiffer than the liner 16 to obtain benefits from use of the Baker device. Applicant's Claims 1 and 19 were previously amended to highlight this teaching away by the cited prior art. More specifically, paragraph 29 of the application as filed states that:

With respect to the flip tab two-stage release liner system, it is important that when the semi-rigid tab is flipped-back on to the portion of the release liner to which it is not attached by adhesive, that the portion of the release liner to which the tab is not attached remains fully adhered to the anchoring member.

Operationally, this limitation describes the establishment of a reinforced "application control edge" on each of the adhesive backed anchoring members which is parallel to the wound edge. The application control edge is established by flipping back the semi-rigid tab (i.e., the first stage of the two stage release liner system). This application control edge enables a user to bend, for example, the first adhesive-backed anchoring member into a U-shape such that only a central portion of the first wound edge of the first anchoring member makes initial contact with the skin. The remaining portion of the first wound edge is then adhered in a very controlled manner by relaxing the U-shaped bend. Achieving the U-shape requires the additional reinforcement provided by the semi-rigid tab as all other parts are soft & flexible.

Baker teaches away from this establishment of an application control edge in numerous

statements in the cited patent. First, contrary to the statement of the Patent Office, the Baker patent describes a device that is applied by two individuals cooperating simultaneously. One individual is controlling the film handle (18) and the second individual is controlling the liner handle 22 (see column 16, lines 53-57). Thus, in the Baker invention, an individual physically controls the leading edge of the film by holding a handle attached to the leading edge of the film. In the present invention, on the other hand, the leading edge of the film (the wound edge of an adhesive-backed anchoring member) is controlled at a distance, by a single user, by virtue of the fact that the semi-rigid tab attached to the release liner, when flipped back onto the portion of the release liner to which it is not attached by adhesive, that the portion of the release liner to which the tab is not attached remains fully adhered to the anchoring member. Figure 1B of the Baker patent clearly demonstrates that the important limitation introduced into Applicant's Claims 1 and 19 is not met.

As discussed above, the proposed combination of Lebner and Baker teaches away from Applicant's invention, for example, Column 8, lines 45-66 make clear that it is not essential to the Baker invention that the liner handle 18 be stiff. In particular, lines 57-58 make clear that the liner handle 18 may be made of the same material as the liner 16. Such a material selection would be inconsistent with Applicant's invention and, therefore, represents a teaching away.

Rejection of Claims 2, 4, 20 and 22 Under 35 USC 103(a)

Claims 2, 4, 20 and 22 have been rejected under 35 USC 103(a) as being unpatentable over U.S. Patent No. 6,329,564 B1 to Lebner in view of U.S. Patent No. 5,979,450 to Baker et al. Claims 2 and 4 are dependent on Claim 1 and Claims 20 and 22 are dependent on Claim 19. It is respectfully submitted that, from the standpoint of a rejection under 35 USC 103, Applicant's arguments as set forth above in connection with Claims 1-13 and 19-32 apply with equal force to the rejection of Claims 2, 4, 20 and 22.

Rejection of Claims 8 and 26 Under 35 USC 103(a)

Claims 8 and 26 have been rejected under 35 USC 103(a) as being unpatentable over U.S.

Patent No. 6,329,564 B1 to Lebner in view of U.S. Patent No. 5,979,450 to Baker et al. Claim 8 is dependent on Claim 1 and Claim 26 is dependent on Claim 19. It is respectfully submitted that, from the standpoint of a rejection under 35 USC 103, Applicant's arguments as set forth above in connection with Claims 1-13 and 19-32 apply with equal force to the rejection of Claims 8 and 26.

Rejection of Claims 3, 5-7, 10-12, 21, 23-25, 28-30 and 32 Under 35 USC 103(a)

Claims 3, 5-7, 10-12, 21, 23-25, 28-30 and 32 have been rejected under 35 USC 103(a) as being unpatentable over U.S. Patent No. 6,329,564 B1 to Lebner in view of U.S. Patent No. 5,979,450 to Baker et al. Claims 3, 5-7, 10-12 are dependent on Claim 1 and Claims 21, 23-25, 28-30 and 32 are dependent on Claim 19. It is respectfully submitted that, from the standpoint of a rejection under 35 USC 103, Applicant's arguments as set forth above in connection with Claims 1-13 and 19-32 apply with equal force to the rejection of Claims 3, 5-7, 10-12, 21, 23-25, 28-30 and 32.

Rejection of Claims 13 and 31 Under 35 USC 103(a)

Claims 13 and 31 have been rejected under 35 USC 103(a) as being unpatentable over U.S. Patent No. 6,329,564 B1 to Lebner in view of U.S. Patent No. 5,979,450 to Baker et al. Claims 13 is dependent on Claim 1 and Claims 31 is dependent on Claim 19. It is respectfully submitted that, from the standpoint of a rejection under 35 USC 103, Applicant's arguments as set forth above in connection with Claims 1-13 and 19-32 apply with equal force to the rejection of Claims 13 and 31.

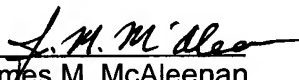
For the above reasons, Applicant respectfully submits that independent claims 1 and 19 are allowable over any proper combination of Lebner in view of Baker. Claims 2-13 and 20-34 are also allowable over of Lebner in view of Baker because of their dependency from allowable base respective claims 1 and 19. Withdrawal of the rejection of claims 1-13 and 19-34 is respectfully requested.

CONCLUSION

In view of the foregoing, it is submitted that none of the references of record, either taken alone or in any proper combination thereof, anticipate or render obvious Applicant's invention, as recited in each of claims 1-13 and 19-34. The applied references of record have been discussed and distinguished, while significant claimed features of the present invention have been pointed out.

Accordingly, reconsideration of the outstanding Office Action and allowance of the present application and all the claims therein are respectfully requested and now believed to be appropriate.

Respectfully submitted,
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